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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/834,410	04/12/2001	Toyohiro Sawada	019941-000510US	3651

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EXAMINER	
YOUNG, MICAH PAUL	
ART UNIT	**PAPER NUMBER**
1618	

MAIL DATE	DELIVERY MODE
01/04/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/834,410	SAWADA ET AL.	
	Examiner	Art Unit	
	MICAH-PAUL YOUNG	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 August 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,5-7,13-15,18-21 and 24-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,5-7,13-15,18-21 and 24-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Acknowledgment of Papers Received: Amendments/Response dated 8/25/09.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 3, 5-7, 13-15, 18-21 and 24-36 rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of Giannini et al (USPN 4,925,674 hereafter '674) in view of Sako et al (EP 0 661 045 hereafter '045) and Taniguchi et al (EP 0 709 386 hereafter '386).

The '674 patent discloses an amoxicillin containing granule formulation where the core granule comprises sucrose and is coated with amoxicillin (col. 5, lin. 3-15). The coated drug core further comprises a binder such as polyvinyl acetate phthalate, not a hydrogel polymer (col. 5, lin. 16). The coated drug core is further coated with a combination of ethylcellulose and

polyethylene glycol (col. 5, lin. 45-col. 6, lin. 24). Ethylcellulose is a hydrogel forming polymer and polyethylene glycol is a hydrophilic polymer.

The reference differs in its disclosure of the specific hydrogel polymer. The reference is however silent to the specific fillers, and active agents of the instant claims. These fillers are well known in the art as shown in the '045 patent. Likewise the active agents are well known as seen in the '386 patent.

The '045 reference teaches a compression molded oral formulation comprising a core comprising a drug (pg. 3, lin. 1-29), along with solubilizers that help improve the solubility of the drug in water such as citric acid, tartaric acid, and polyethylene glycol (pg 3, lin. 30-43). The core is coated with a hydrogel formulation comprising a hydrophilic base such as polyethylene glycols (pg. 3, lin. 49-pg. 4, lin. 7) and hydrogel-forming polymers with viscosities not less than 1000 cps in 1% aqueous solution, and molecular weight above 2,000,000 such as polyethylene oxides (pg. 4, lin. 8-51). The formulation further includes yellow iron sesquioxide (pg. 13, lin. 10-15). The drugs include lidocaine, nicardipine, and quindine, agents that are all metabolized by CYP3A4 (pg. 3, lin. 5-25). Upon administration, water is absorbed into the core of the formulation during its stay in the upper intestine, essentially dissolving the core and releasing the drug slowly as it travels to the colon (pg 2, lin. 35-40). The drug is present in the formulation in concentrations from 80-85%, the hydrophilic base is present in concentration from 5-80%, the hydrogel-forming polymer is present in concentration greater than 16% and solubilizing agent that aids in water absorption into the core is present in concentrations from 15-90% (pg. 3 lin. 25-pg. 5, lin. 13). The formulation remains within the digestive tract for up to 12 hours and within that time the formulation dissolves 70-100% (figures). The reference establishes the

level of skill in the art regarding specific fillers and their relation to compression coatings and hydrogel-forming compression tablets. The artisan of ordinary skill would have been able to include the fillers of the '045 reference into the '674 since both formulation disclose similar formulations.

The '386 patent discloses a fused benzazepine derivative, which can be useful as a vasopressin antagonist. The drug can be formulated into tablets using conventional excipients such as sucrose, gelatin and hydroxypropylcellulose (pg. 27, lin. 23 – 37). The drug of the invention can be used in the treatment of various disorders ranging from cerebrovascular disease to renal disorders (pg. 23, lin. 24 – 44). A skilled artisan would be able to include the compound of '386 into the formulation of '674 since the '674 reference uses similar drugs to treat similar disorders.

Furthermore the claims differ from the reference by reciting various concentrations of the active ingredient(s). However, the preparation of various pharmaceutical compositions having various amounts of the active is within the level of skill of one having ordinary skill in the art at the time of the invention. It has also been held that the mere selection of proportions and ranges is not patentable absent a showing of criticality. *See* In re Russell, 439 F.2d 1228 169 USPQ 426 (CCPA 1971).

Regarding the concomitant drug administration, the '674 patent discloses a formulation comprising multiple drug cores, each of which is coated with the same mixture of the hydrophilic and hydrogel forming polymers. These drugs would be separated by the same coating as the instant claims and as such would have the same cocomitant and *in vivo* properties of the instant claims.

With these thing in mind it would have been obvious to combine the prior art in order to provide a stable controlled release formulation with improved lower digestive tract release. Following the suggestions of the '674 patent to coat the core tablet with a mixture of polyethylene glycol and oxide, it would have been obvious to use the fillers of the '045 patent in order to provide proper release of the core active agents. It would have been obvious to substitute the active agent of the '386 patent into the combination. One of ordinary skill in the art would have been motivated to combine the suggestions and teachings of the prior art with an expected result of a stable controlled release formulation useful in alleviating undesirable drug interactions.

Response to Arguments

Applicant's arguments with respect to claims 1, 3, 5-7, 13-15, 18-21, and 24-36 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICAH-PAUL YOUNG whose telephone number is (571)272-0608. The examiner can normally be reached on Monday-Friday 8:00-5:30; every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

/MICAH-PAUL YOUNG/
Examiner, Art Unit 1618